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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,089

03/18/2004

Gholam A. Peyman

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10/05/2007

ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P.

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SUITE 600

WASHINGTON,, DC 20036

EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,089	Applicant(s) PEYMAN, GHOLAM A.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 24-30, 32-42 and 44-46 is/are rejected.
- 7) ☒ Claim(s) 22, 23, 31 and 43 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10142005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt is acknowledged of the information disclosure statement filed

10/14/2007.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-12, 14-21, 24-30, 32-42, 44-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-31 of copending Application No. 10/803,090 (US'090). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'090 claims a method of suppressing pain and inhibiting irritation by

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providing a carrier with at least one bioactive and an anti irritant amount of a sweetener which is then contacted with body tissues (see claim 16). The carrier may be aqueous (claim 17) or a gum base (claim 26). Administration may be to the mouth (claim 18). Anti- inflammatories are set out in claim 20. The pH of the composition is set out in claims 21-24, with the particular acids added to include ascorbic acid. Other bioactives are found in claim 25. Saccharin, cyclamates and aspartame are set out in claim 27. Stabilizers such as cysteine, magnesium salts, phosphonic acid and metabisulfite derivatives are set out in claims 30 and 31. Therefore, the ordinary practitioner would have found it well within their skill to claim the instant formulation with a reasonable expectation of the suppression of irritation and pain given the claims of copending US'090. The instant claims would have been obvious to one of ordinary skill at the time of invention given the claims of copending US'090

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-14, 24-26, 29, 30, 32-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,436,429 (US'429). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'429 claims a method of suppressing pain and irritation by administering a carrier, a bioactive and an anti irritant amount of a sweetener (see claim 1). The carrier may be water soluble (see claim 2). Administration may be to the mouth (claim 3). The pH of the composition may be less

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than 6 (claim 4), 2 to 5 (claim 5), and less than 4 (claims 6 and 7). Specific acids added to adjust the pH are set out in claim 7. Bioactives used in the composition are set out in claim 8. The carrier may have a chewing gum base (claim 9). Artificial sweeteners are set out in claim 10. The percentage of sweeteners maybe at least 10% (claim 11).

Alkaline agents may be added to the composition at claim 12. Therefore, the ordinary practitioner would have found it well within their skill to claim the instant formulation with a reasonable expectation of the suppression of irritation and pain given the claims of copending US'429. The instant claims would have been obvious to one of ordinary skill at the time of invention given the claims of copending US'429

Claims 1-5, 24-26, 32-34, 39 and 40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,223,416 (US'416). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'416 claims a method of comprising an NSAID with an anti-irritant amount of a sweetener.(see claim 1). A tetracycline antibiotic may also be included (see claim 4). Therefore, the ordinary practitioner would have found it well within their skill to claim the instant formulation with a reasonable expectation of the suppression of irritation and pain given the claims of copending US'416. The instant claims would have been obvious to one of ordinary skill at the time of invention given the claims of copending US'416

US Patent Nos. 4,882,153 (Yang et al) and 5,858,391 (Cuca et al) are cited for their disclosure of a drug delivery system in a gum base which may further contain a sweetener. No disclosure is made of the claimed anti irritant or pain suppression property of said sweeteners.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

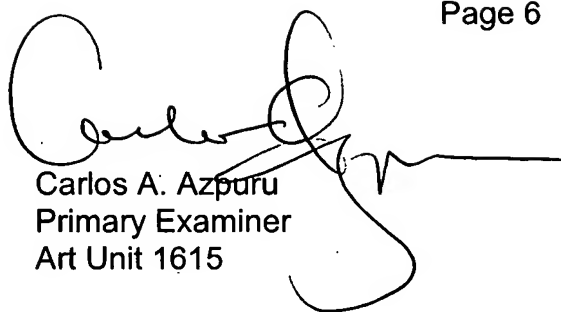
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Carlos A. Azpuru
Primary Examiner
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